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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,046	09/26/2003	David M. Gravett	110129.430	8047

41551 7590 09/27/2006

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,046	GRAVETT ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-231* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-231* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :1/03/06; 2/02/06; 6/9/05; 7/5/05; 7/23/04; 5/19/04.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-93, drawn to a device comprising a therapeutic agent and a mesh comprising a biodegradable polymer, classified in class 424, subclass 426.

II. Claims 94-97, drawn to device comprising first and second therapeutic agents and mesh comprising biodegradable polymer, classified in class 424, subclass 446.

III. Claims 98-188, drawn to method for improving or maintaining a body passageway lumen or cavity, the method comprises delivering a delivery device to the body passageway or cavity a device comprising therapeutic agent and a mesh that comprises biodegradable polymer, classified in class 604, subclass 891.1.

IV. Claims 193-206, drawn to method for producing a delivery device, classified in class 424, subclass 423.

V. Claims 207-221, drawn to composition comprising therapeutic agent and mesh that comprises biodegradable polymer, classified in class 424, subclass 443.

VI. Claims 222-225, drawn to delivery device comprising a mesh and copolymer of lactide and glycolide and therapeutic agent and further comprising methoxy PEG-PLA block polymer polymeric carrier, classified in class 424, subclass 426.

VII. Claims 226-231, drawn to method for drug delivery, classified in class 424, subclass 445.

VIII. Claims 189-192, drawn to method of treating or preventing intimal hyperplasia, the method comprises delivering a delivery device that comprises therapeutic

agent and a mesh that is made of biodegradable polymer to the site of interest, classified in class 424, subclass 426.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are I) device that comprises one therapeutic agent and II) device that comprises first and second therapeutic agent.

3. Inventions I and II are unrelated to invention V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions I and II have specific structure as devices and invention V is not defined by any specific structure and could be solution or liquid or solid or emulsion.

4. Inventions I, II are unrelated to invention VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions I and II have specific structure as devices and invention V is not defined by any specific structure and could be solution or liquid or solid or emulsion. The inventions are capable of supporting different patents within the art.

5. Inventions IV and I, II, VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as

claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process as claimed in invention IV can be used to make materially different product.

6. Inventions I, II, VI and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device as claimed can be used in materially different process of using the device.

7. Inventions I, II, VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device as claimed can be used in materially different process of using the device.

8. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction were not required because the

inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

10. Claims 1, 98, 193, 207, 222 and 226 are generic to the following disclosed patentably distinct species: different mesh designs, different biodegradable polymers, different therapeutic agents are claimed.

11. A) If applicant elects Group I, applicant must further elect

a) one specific biodegradable polymer, b) a film or wrap or gel or foam of mold or coating, c) polymeric carrier or non-polymeric carrier, d) anti-angiogenic agent or anti-inflammatory agent or statin or antibiotic neoplastic agent or antibacterial agent or immunosuppressive antibiotic, and e) single layer or multiple layered mesh. C(i) Furthermore, if applicant elects polymeric carrier, then applicant must further elect a specific ABA biodegradable polymer carrier or BAB biodegradable polymer carrier; and C (ii) if applicant elects non-polymeric carrier, applicant must further elect hyaluronic acid or chitosan or alginate or poly(urethane) or poly(hydroxyethylmethacrylate),

d i) if applicant elects anti-angiogenic agent, applicant must further elect paclitaxel or doxorubicin or fucoidon or analogue or derivative,

d ii) if applicant elects a statin, applicant must further elect cervistatin or analogue or derivative,

d iii) if applicant elects immunosuppressive antibiotic, applicant must also elect sirolimus or everolimus or tacrolimus.

11. B) If applicant elects Group II, applicant is required to elect a device where the first and second therapeutic agents have the same composition or where the first and second therapeutic agents have different compositions.

11. C) If applicant elects Group III, applicant must further elect one specific biodegradable polymer, b) a film or wrap or gel or foam of mold or coating, c) polymeric carrier or non polymeric carrier, d) angiogenic agent or anti-inflammatory agent or satin or antibiotic neoplastic agent or antibacterial agent or antifungal agent or antiviral agent or immunosuppressive antibiotic, e) one specific disclosed body passageway or specific disclosed body cavity, f) one specific disclosed condition that is improved

c i) if applicant elects a polymeric carrier, applicant must further elect a specific ABA biodegradable polymeric carrier or BAB biodegradable polymeric carrier or hyaluronic acid or chitosan or alginate or polyurethane or poly(hydroxyethylmethacrylate,

c ii) if applicant elects non-polymeric carrier, applicant must further elect sucrose acetate isobutyrate or stearate or sucrose oleate or refined microcrystalline paraffin wax,

d i) if applicant elects anti-angiogenic agent, applicant must further elect paclitaxel or doxorubicin or fucoidon or analogue or derivative,

d ii) if applicant elects a statin, applicant must further elect cervistatin or analogue or derivative,

d iii) if applicant elects immunosuppressive antibiotic, applicant must also elect sirolimus or everolimus or tacrolimus.

11. D) If applicant elects Group V, applicant must further elect one specific disclosed therapeutic agent; one specific disclosed biodegradable polymer.

11. E) If applicant elects Group VII, applicant must further elect one specific disclosed site of treatment.

11. F) if applicant elects Group VIII, applicant must further elect one specific disclosed anastomotic site.

12. The species are independent or distinct because each is capable of support a patent within the art. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

13. A telephone call was not made to applicant to request an oral election to the above restriction requirement in view of the complexity of the requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Blessing Fubara
Patent Examiner
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